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K003114

SUMMARY OF SAFETY AND EFFECTIVENESS DATA

October 3, 2000

Submitted By: NuMED, Inc. , 2880 Main St., Hopkinton, NY 12965 (Ph) 315-328-4491

Contact Person: Nichelle LaFlesh

Device Name: NuMED Tyshak and Z-Med PTV Catheters; Class II

Predicate Devices: NuMED Tyshak and Z-MED PTV Catheters

Device Description: The Tyshak™, and Z-MED™ PTV Catheters are coaxial over-the-wire catheters with a balloon near the distal tip. They are available in varied sizes depending on which catheter that you need. The available sizes are below. One lumen permits guidewire insertion to facilitate advancement of the catheter into the pulmonary valve while the other lumen is for balloon inflation and deflation.

The balloon of the Tyshak™, and Z-MED™ models are all made of a non-compliant polyethylene, however the Z-MED™ balloon is manufactured with an increased wall thickness. The increased wall thickness allows the balloon to achieve a higher pressure before rupture occurs. The balloons are designed to inflate to a specific diameter at a given pressure. The change in diameter is minimal over the range of inflation pressures.

The catheter body ends proximally in a molded 'Y' connector with a guidewire port and a balloon extension. The balloon extension is marked with the product lot number and the balloon size.

The outer body and inner body tubing is made of Pebax. The area under the balloon is enhanced with either one or two radiopaque platinum image bands depending on the model. If marked with one image band, it is centered under the midpoint of the balloon. If it is marked with two image bands, they are located under the shoulders of the balloon.

The drawings for the NuMED PTV catheters are included on the following pages.

This catheter is of the same design and construction as the NuMED PTV catheters for which the 510(K) has been approved. The only difference is the additional sizes.

Biocompatibility Testing:

The materials used in the NuMED Tyshak and Z-MED PTV Catheters are the same as those used in our PTA Catheters (510(k) #K931009) and PTV Catheters (510(k) #K991977) which were tested for biocompatibility in compliance with the Tripartite Biocompatibility Guidance for Medical Devices.

Test results indicate that all materials demonstrate the biocompatibility of the NuMED catheter and are on file at NuMED, Inc.

Laboratory (Bench) Testing: All bench testing was performed in accordance with GMP's and the results are kept on file at NuMED, Inc.

Intended Use: This catheter is recommended for Percutaneous Transluminal Valvuloplasty (PTV) of the pulmonary valve.

- A patient with isolated pulmonary stenosis.
- A patient with valvular pulmonary stenosis with other minor congenital heart disease that does not require surgical intervention.

Comparison Information:

MODEL:	NUMED TYSHAK AND Z-MED	NUMED TYSHAK AND Z-MED
Indications:	<p>This catheter is recommended for Percutaneous Transluminal Valvuloplasty (PTV) of the pulmonary valve.</p> <ul style="list-style-type: none"> ▪ A patient with isolated pulmonary stenosis. ▪ A patient with valvular pulmonary stenosis with other minor congenital heart disease that does not require surgical intervention. 	<p>This catheter is recommended for Percutaneous Transluminal Valvuloplasty (PTV) of the pulmonary valve.</p> <ul style="list-style-type: none"> ▪ A patient with isolated pulmonary stenosis. ▪ A patient with valvular pulmonary stenosis with other minor congenital heart disease that does not require surgical intervention.
Introducer:	<p>Tyshak – 4Fr-12Fr Z-MED – 6Fr-12Fr</p>	<p>Tyshak – 4Fr-12Fr Z-MED – 6Fr-12Fr</p>
Shaft Size:	<p>Tyshak – 3.5Fr-9Fr Z-MED – 5Fr-9Fr</p>	<p>Tyshak – 3.5Fr-9Fr Z-MED – 5Fr-9Fr</p>
Guidewire Size:	<p>Tyshak – 0.018”-0.035” Z-MED – 0.025”-0.035”</p>	<p>Tyshak – 0.018”-0.035” Z-MED – 0.025”-0.035”</p>
Usable Length:	<p>Tyshak – 70cm – 120cm Z-MED – 85cm-120cm</p>	<p>Tyshak – 70cm – 120cm Z-MED – 85cm-120cm</p>
Balloon Diameter:	<p>Tyshak – 2mm – 25mm Z-MED – 2mm – 30mm</p>	<p>Tyshak – 2mm – 25mm Z-MED – 2mm – 30mm</p>
Balloon Length:	<p>Tyshak – 1cm-15cm Z-MED – 1cm-15cm</p>	<p>Tyshak – 1cm-15cm Z-MED – 1cm-15cm</p>
Materials:	<p>Shaft: Pebax Balloon: Besno Image Band: Platinum</p>	<p>Shaft: Pebax Balloon: Besno Image Band: Platinum</p>
Construction:	<p>Coaxial construction with distally mounted non-compliant balloon.</p>	<p>Coaxial construction with distally mounted non-compliant balloon.</p>



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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NuMed, Inc.
c/o Ms. Nichelle LaFlesh
Regulatory Affairs Manager
P.O. Box 129
Nicholville, NY 12965

Re: K003114
Trade Name: NuMed, Inc. Tyshak and Z-Med PTV Catheter
Regulatory Class: II (two)
Product Code: LIT, and DQY
Dated: October 4, 2000
Received: October 5, 2000

Dear Ms. LaFlesh:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

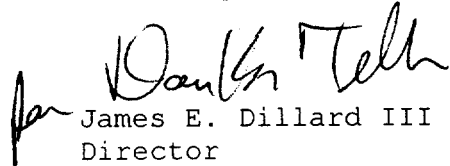
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 - Ms. Nichelle Laflesh

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

James E. Dillard III
Director

Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications For Use

510(k) Number (if known): K003114

Device Name: **NuMED Tyshak and Z-MED PTV
Catheters**

Indications For Use:

This catheter is recommended for Percutaneous Transluminal Valvuloplasty (PTV) of the pulmonary valve.

- A patient with isolated pulmonary stenosis
- A patient with valvular pulmonary stenosis with other minor congenital heart disease that does not require surgical intervention.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use _____

Wendy Telli
Division of Cardiovascular & Respiratory Devices
510(k) Number K003114

(Optional Format 1-2-96)